DEPARTMENT OF HEALTH & HUMAN SERVICES

9467/d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 27, 2004 WL 36-04

Carl W. Grodach, R.Ph.
President
Clinical Pharmacies, Inc.
21622 Surveyor Circle, # 8C
Huntington Beach, CA 92646

Dear Mr. Grodach:

On February 19, February 23, March 1, and March 2, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility in Huntington Beach, California, which manufactures dialysate concentrates. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h).

The inspection revealed that the devices are adulterated within the meaning of Section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements set forth in FDA's Quality System (QS) Regulation, codified in Title 21, Code of Federal Regulations (CFR), Part 820. The investigator noted the following QS Regulation violations, which are also listed in the FDA Form 483 provided to your facility at the end of the inspection:

1. Failure to establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured, and that meets the requirements of 21 CFR Part 820, as required by 21 CFR 820.5. For example,

- Management with executive responsibility has not ensured that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR 820.20(a).

- Management with executive responsibility has not established policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a).

- Failure to establish a quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured, as required by 21 CFR 820.20(d).

- Management with executive responsibility has not appointed a member of management with established authority over and responsibility for ensuring that quality system requirements are effectively established and maintained and for reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3).

- No procedures for conducting management reviews have been established, and no management reviews of the quality system have been conducted, in accordance with 21 CFR 820.20(c).

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit ensuring that all complaints are processed in a uniform and timely manner, and that complaints are evaluated to determine whether complaints represent events that are required to be reported to FDA under 21 CFR Part 803, as required by 21 CFR 820.198(a)(1), (3).

3. Failure to establish procedures for quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.

4. Failure to establish and maintain procedures for implementing corrective and preventive action including requirements for analyzing sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR 820.100(a)(1).

5. Failure to establish and maintain procedures for document control and designate an individual(s) to review documents for adequacy and approval prior to issuance or when changes have been made to the documents, as required by 21 CFR 820.40.

6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

7. Process validation activities and results have not been documented, as required by 21 CFR 820.75(a).

8. Failure to establish and maintain procedures for addressing the identification, documentation, evaluation, segregation, disposition and investigation of nonconforming product, as required by 21 CFR 820.90.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and FDA implementing regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters pertaining to medical devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

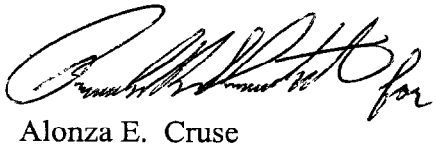
You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to identify and prevent the recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions regarding this letter, please contact Dannie E. Rowland, Senior Compliance Officer at 949-608-4448.

Your written reply should be addressed to:

Pam Schweikert
Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse
District Director

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320